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PTO/SB/088 (08-03)

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| Application Number | 09/747,521 |
| Filing Date | December 21, 2000 |
| First Named Inventor | Galloway |
| Art Unit | 1645 |
| Examiner Name | Shahnan Shah |
| Attorney Docket Number | 22727/04079 |

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| ks | | ARORA et al., "Fusions of anthrax toxin lethal factor to the ADP-ribosylation domain of Pseudomonas exotoxin A are potent cytotoxins which are translocated to the cytosol of mammalian cells", <u>J. Biol. Chem.</u> (1992) Volume 267, Pages 15542-15548. | |
| | | ARORA and LEPLA, "Residues 1-254 of anthrax toxin lethal factor sufficient to cause cellular uptake of fused polypeptides", <u>J. Biol. Chem.</u> (1993) Volume 268, Pages 3334-3341. | |
| | | BROSSIER et al., "Role of toxin functional domains in anthrax pathogenesis", <u>Infect. Immun.</u> (2000) Volume 68, Pages 1781-1786. | |
| | | CIRINO et al., "Disruption of anthrax toxin binding with the use of human antibodies and competitive inhibitors", <u>Infect. Immun.</u> (1999) Volume 67, Pages 2657-2963. | |
| | | DENIS-MIZE et al., "Analysis of immunization with DNA encoding Pseudomonas aeruginosa exotoxin A", <u>FEMS Immunol. Med. Microbiol.</u> (2000) Volume 24, Pages 147-154. | |
| | | DONNELLY et al., "DNA Vaccines", <u>Annu. Rev. Immunol.</u> (1997) Volume 15, Pages 617-648. | |
| | | DUESBERY et al., "Proteolytic inactivation of MAP-kinase-kinase by anthrax lethal factor", <u>Science</u> (1998) Volume 280, Pages 734-737. | |
| | | FELLOWS et al., "Efficacy of a human anthrax vaccine in guinea pigs, rabbits, and rhesus macaques against challenge by Bacillus anthracis isolates of diverse geographic origin", <u>Vaccine</u> (2001) Volume 19, Pages 3241-3247. | |
| | | FELTQUATE et al., "Different T helper cell types and antibody isotypes generated by saline and gene gun DNA immunization", <u>J. Immunol.</u> (1997) Volume 158, Pages 2278-2284. | |
| ks | | FRIEDLANDER, "Macrophages are sensitive to anthrax lethal toxin through an acid-dependent process", <u>J. Biol. Chem.</u> (1986) Volume 261, Pages 7123-7126. | |

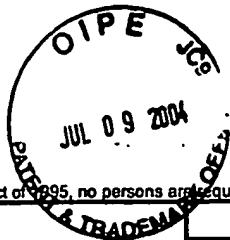
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| Art Unit | 1645 |
| Examiner Name | Shahnan Shah |
| Attorney Docket Number | 22727/04079 |

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| FS | | GORDON et al., "Proteolytic activation of a bacterial toxins by eukaryotic cells is performed by furin and by additional cellular proteases", <u>Infect. Immun.</u> (1995) Volume 63, Pages 82-87. | |
| | | GUIDI-RONTANI et al., "Anthrax lethal toxin-induced mitogenic response of human T-cells", <u>FEMS Lett.</u> (1997) Volume 157, Pages 285-289. | |
| | | GUIDI-RONTANI et al., "Germination of Bacillus anthracis within alveolar macrophages", <u>Mol. Microbiol.</u> (1999) Volume 31, Pages 9-17. | |
| | | GUPTA et al., "Involvement of residues 147VYVEIGK153 in binding of lethal factor to protective antigen of Bacillus anthracis", <u>Biochem. Biophys. Res. Commun.</u> (2001) Volume 280, Pages 158-163. | |
| | | HADDAD et al., "Comparative study of DNA-based immunization vectors: Effect of secretion signals on the antibody response in mice", <u>FEMS Immunol. Med. Microbiol.</u> (1997) Volume 18, Pages 193-202. | |
| | | IVINS et al., "Experimental anthrax vaccines: efficacy of adjuvants combined with protective antigen against an aerosol Bacillus anthracis spore challenge in guinea pigs", <u>Vaccine</u> (1995) Volume 13, Pages 1779-1784. | |
| | | IVINS and WELKOS, "Recent advances in the development of an improved, human anthrax vaccine", <u>Eur. J. Epidemiol.</u> (1988) Volume 4, Pages 12-19. | |
| | | KLIMPEL et al., "Anthrax toxin protective antigen is activated by a cell surface protease with the sequence specificity and catalytic properties of furin", <u>Proc. Natl. Acad. Sci. USA</u> (1992) Volume 89, Pages 10277-10281. | |
| | | KLIMPEL et al., "Anthrax toxin lethal factor contains a zinc metalloproteinase consensus sequence which is required for lethal toxin activity", <u>Mol. Microbiol.</u> (1994) Volume 13, Pages 1093-1100. | |
| | | LEPPLA, "Anthrax toxin edema factor: a bacterial adenylate cyclase that increases cyclic AMP concentrations of eukaryotic cells", <u>Proc. Natl. Acad. Sci. USA</u> (1982) Volume 79, Pages 3162-3166. | |

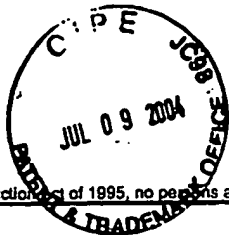
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First Named Inventor Galloway

Art Unit 1645

Examiner Name Shannan Shah

Attorney Docket Number 22727/04079

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| lc | | LEPPLA, "Production and purification of anthrax toxin", <u>Methods Enzymol.</u> (1988) Volume 165, Pages 103-116. | |
| | | LEPPLA et al., "Proteolytic activation of anthrax toxin bound to cellular receptors", <u>Bacterial protein toxins</u> (F.J. Fehrenbach et al., Gustav Fischer, New York, NY) Pages 111-112. | |
| | | LITTLE and IVINS, "Molecular pathogenesis of Bacillus anthracis infection", <u>Microbes Infect.</u> (1999) Volume 2, Pages 131-139. | |
| | | LITTLE et al., "Production and characterization of monoclonal antibodies to the protective antigen of Bacillus anthracis toxin", <u>Infect. Immun.</u> (1988) Volume 56, Pages 1807-1813. | |
| | | MANICKAN et al., "DNA vaccines a modern gimmick or a boon to vaccinology?", <u>Crit. Rev. Immunol.</u> (1997) Volume 17, Pages 139-154. | |
| | | MIKESELL et al., "Evidence for plasmidmediated toxin production in Bacillus anthracis", <u>Infect. Immun.</u> (1983) Volume 39, Pages 371-376. | |
| | | MILNE et al., "Anthrax protective antigen forms oligomers during intoxication of mammalian cells", <u>J. Biol. Chem.</u> (1994) Volume 269, Pages 20607-20612. | |
| | | PANNIFER et al., "Crystal structure of the anthrax lethal factor", <u>Nature</u> (2001) Volume 414, Pages 229-233. | |
| | | PARK and LEPPLA, "Optimized production and purification of Bacillus anthracis lethal factor", <u>Protein Expr. Purif.</u> (2000) Volume 18, Pages 293-302. | |
| w | | PELLIZARI et al., "Anthrax lethal factor cleaves MKK3 in macrophages and inhibits the KOS.UFB-induced release of NO and TNF", <u>FEBS Lett.</u> (1999) Volume 462, Pages 199-204. | |

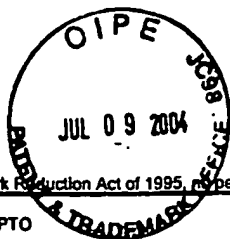
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| 147 | | PETOSA et al., "Crystal structure of the anthrax toxin protective antigen", <u>Nature</u> (1997) Volume 385, Pages 833-838. | |
| | | PEZARD et al., "Contribution of individual toxin components to virulence of <i>Bacillus anthracis</i> ", <u>Infect. Immun.</u> (1991) Volume 59, Pages 3472-3477. | |
| | | PEZARD et al., "Protective immunity induced by <i>Bacillus anthracis</i> toxin-deficient strains", <u>Infect. Immun.</u> (1995) Volume 63, Pages 1369-1372. | |
| | | PRICE, "Protection against anthrax lethal toxin challenge by genetic immunization with a plasmid encoding the lethal factor protein", <u>Infect. Immun.</u> (2001) Volume 69, Number 7, Pages 4509-4515. | |
| | | SINGH et al., "The chymotrypsin-sensitive site, FFD315, in anthrax toxin protective antigen is required for translocation of lethal factor", <u>J. Biol. Chem.</u> (1994) Volume 269, Pages 29039-29046. | |
| | | VARUGHESE et al., "Internalization of a <i>Bacillus anthracis</i> protective antigen c-Myc fusion protein mediated by cell surface anti-c-Myc antibodies", <u>Mol. Med.</u> (1998) Volume 4, Pages 87-95. | |
| | | VITALE et al., "Anthrax lethal factor cleaves the N-terminus of MAPKK and induces tyrosine/threonine phosphorylation of MAPKs in cultured macrophages", <u>Biochem. Biophys. Res. Commun.</u> (1998) Volume 248, Pages 706-711. | |
| | | WELKOS et al., "Sequence and analysis of the DNA encoding protective antigen of <i>Bacillus anthracis</i> ", <u>Gene</u> (1988) Volume 69, Pages 287-300. | |
| | | ZAUCHA et al., "The pathology of experimental anthrax in rabbits exposed by inhalation and subcutaneous inoculation", <u>Arch. Pathol. Lab. Med.</u> (1998) Volume 122, Pages 982-992. | |
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